ROBITUSSIN PEAK COLD MULTI-SYMPTOM COLD- dextromethorphan hydrobromide, guaifenes in, and phenylephrine hydrochloride liquid GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 10 ml)

Dextromethorphan HBr, USP 20 mg Guaifenesin, USP 200 mg Phenylephrine HCl, USP 10 mg

Purposes

Cough suppressant Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
 - nasal congestion
 - cough due to minor throat and bronchial irritation

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or

stimulant.

When using this product do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	10 ml every 4 hours
children under 12 years	do not use

Other information

- each 10 ml contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, glycerin, menthol, natural & artificial flavor, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

For most recent product information,

visit www.robitussin.com

Distributed by:

Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

ADULT

Robituss in[®]

PEAK COLD

Multi-Symptom Cold

DEXTROMETHORPHAN HBr (Cough Suppressant) GUAIFENESIN (Expectorant) PHENYLEPHRINE HCl (Nasal Decongestant)

Relieves:

- Cough
- Nasal Congestion
- Mucus

Non-Drowsy CF

For Ages 12 & Over 4 FL OZ (118 ml)





ROBITUSSIN PEAK COLD MULTI-SYMPTOM COLD

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8742
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	RED (clear red liquid)	Score	
Shape		Size	
Flavor	BERRY (berry-citrus flavor), CITRUS	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8742-14	1 in 1 CARTON	06/12/2011	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8742-20	1 in 1 CARTON	06/12/2011	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	06/12/2011	

Labeler - Glaxo SmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 10/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC